

tiologic[®]
easyClean

Processing Instructions.

Cleaning – so easy.





A good decision.

Congratulations on your new tiologic[®] easyClean Wash-Tray.

Machine treatment of the entire instrument set is an essential component of quality assurance. For this reason, Dentaureum Implants has developed the tiologic[®] easyClean Wash-Tray in collaboration with Miele Professional.

This comprehensive system solution meets a new quality requirement in implantology: the automatic washing and disinfection of a completely packed surgical tray.

In the tiologic[®] easyClean, minimal contact surface, an innovative lattice structure and a fine mesh tray ensure the optimal washing of each component.

This innovative cleaning concept considerably simplifies the daily workflow and helps increasing safety, not only during implantation but also during processing. In addition, tiologic[®] easyClean significantly helps saving working time and ensures reproducible machine-treatment results.

Another benefit of tiologic[®] easyClean: during implantation, the instruments can be put back in the corresponding slots after use. Hence, each instrument is always located in the intended place. Mostly, there is no need for manual treatment of individual components, for the fully loaded tiologic[®] easyClean is directly placed in the corresponding basket of the Dental Washer Disinfector.

It is thus an optimal system solution for doctors' surgeries and central treatment centres.



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tioLogic® easyClean Wash-Tray

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Reusability of surgical instruments

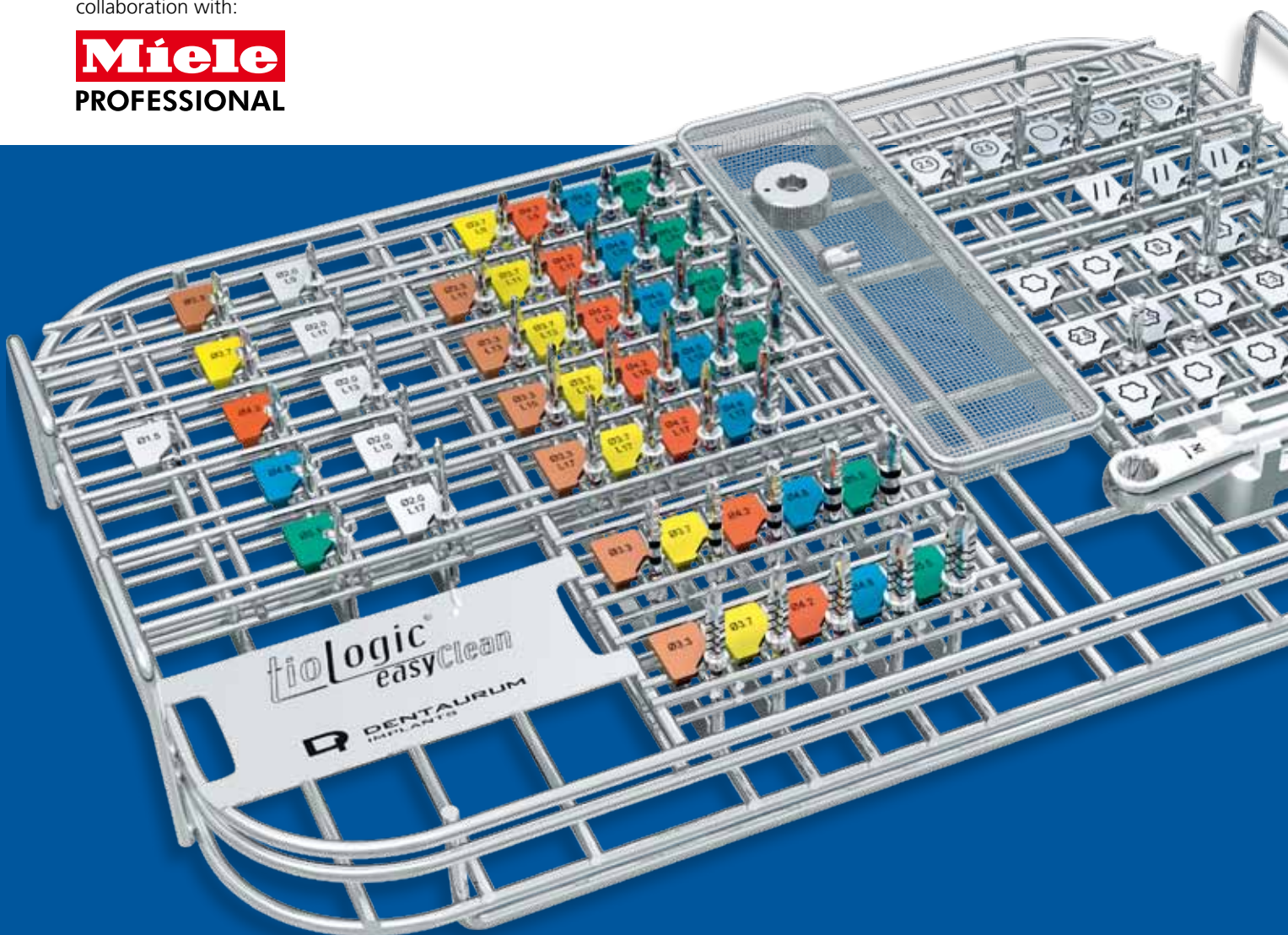
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Cleaning – so easy.

tioLogic® easyClean – the tray for machine processing.¹

Developed in
collaboration with:



The tested tioLogic® easyClean can be excellently cleaned without mechanical pre-cleaning.¹

¹ Cleaning investigation tioLogic® easyClean, AFIP, 2012.



tiologic®
easyClean

Innovative
lattice structure.



Stable fixation spring.



Clear
guidance system.



Reproducible
machine-treatment
results.



The tiologic® easyClean is a Wash-Tray that contains all the rotary instruments and accessory components needed for implantation. They are arranged according to the operation sequence. For optimal orientation there is a colour-coded and laser-labelled plastic clip beside each instrument. The used instruments and accessory components are put back in the corresponding slots directly after each use. This increases safety during implantation as all instruments are always located in the intended place. After implantation, the completely packed tiologic® easyClean is transferred to the machine treatment cycle. Small parts and accessory components to be disassembled are placed in the mesh tray.

Advantages:

Machine treatment of the completely packed surgical tray.

Guaranteed by:

- optimal washing of the components
- minimal contact surface
- innovative lattice structure
- fine mesh tray

Added value for the practice:

- no manual treatment necessary
- reproducible machine treatment results
- saves working time
- no sorting of components necessary

Suitable for doctors' surgeries and central treatment centres.



General instructions.

! Special measures are required with certain instruments.
Please refer to section Reusability of surgical instruments
■ p. 14!

Application.

For reuse, all instruments should be cleaned, disinfected and sterilized before each use. This applies in particular to initial use, as all instruments are supplied non-sterile (clean and disinfect after removing the transport packaging). Thorough cleaning and disinfection is essential for effective sterilization.

The operator is responsible for the sterility of the instruments and should always ensure that only properly validated procedures relating to the unit and the product are used for cleaning, disinfection and sterilization, that the units used (disinfector, sterilizer) are regularly serviced and checked and that the validated parameters are maintained during each cycle.

tioLogic® easyClean instruments can be put back in the tray when they are dirty. Prior to cleaning in the Dental Washer Disinfector, all instruments to be dismantled (torque ratchet, placement aids, etc.) should be disassembled and put in the closable screen basket. After removing loose dirt, tioLogic® easyClean is placed in the upper basket of the Dental Washer Disinfector for cleaning and disinfecting.

The fully loaded tray should then be sterilized in the Aesculap sterilisation container.

The current legal regulations in the relevant country as well as the hygiene regulations of the dental practice or hospital should be adhered to. This applies in particular to the different instructions regarding effective inactivation of prions.

Cleaning and disinfection – Basic instructions.

For washing and disinfecting tioLogic® easyClean, a mechanical procedure should be used (Dental Washer Disinfector). For instruments and accessory components with hollow sections, special processing steps should be observed (see preconditioning).

Preconditioning.

Loose dirt should be removed from the instruments immediately after use (within maximum 2 hours).

Loose dirt should be removed under running water or using a disinfectant solution; the disinfectant should not contain aldehyde (may cause fixation of blood debris) and should have certified efficacy (e.g. DGHM or FDA approved and CE marking); it should also be suitable for disinfection of the instruments and compatible with the instruments (p. 13 section Material resistance). Only a soft brush or a clean, soft cloth should be used for removing dirt manually; metal brushes or steel wool should never be used.

If applicable: rinse all hollow sections of the instruments 5 times using a disposable syringe (minimum volume 5.0 ml).

Note that the disinfectant used for preconditioning is only for personal protection and cannot be regarded as a substitute for subsequent disinfection after cleaning.

Mechanical cleaning/disinfection (disinfector or cleaner/disinfector).

When choosing a disinfector, ensure that

- the efficacy of the disinfector has been certified (e.g. DGHM or FDA approved and CE marking according to DIN EN ISO 15883),
- a certified programme for thermal disinfection (minimum 5 min. at 90 °C/194 °F or an A0 > 3000) is used (with chemical disinfection there is the risk of disinfectant residue on the instruments),
- the programme used is suitable for the instruments and has an adequate number of rinse cycles,
- it uses only water that is sterile or has a low bacteria count (max. 10 bacteria/ml) and is low in endotoxins (max. 0.25 endotoxin units/ml) (e.g. purified water/highly purified water) for rinsing,
- the air used for drying is filtered,
- the disinfector is regularly serviced and checked.

General instructions.

! Special measures are required with certain instruments.
Please refer to section Reusability of surgical instruments
■ p. 14!

Cleaning supplies.

When choosing a cleaning agent system, ensure that

- it is suitable for cleaning metal and plastic instruments,
- provided that thermal sterilization is not used – an additional disinfectant with certified efficacy (e.g. DGHM or FDA approved and CE marking) is used and that it is compatible with the cleaning agent used,
- the chemicals used are compatible with the instruments (p. 13 section Material resistance),
- the concentrations given by the cleaning agent and disinfectant manufacturer must be strictly adhered to.

Sequence – Cleaning.

1. Removing loose dirt from instruments and tray.
2. Dismantling instruments (p. 14 Reusability of surgical instruments).
3. Placing the dismantled instruments in the basket and sealing it.
4. Inserting remaining instruments in the intended places.
5. Putting the equipped tioLogic® easyClean in the upper basket of the Dental Washer Disinfector.

6. Starting the cleaning programme of the Dental Washer Disinfector according to manufacturer's instructions.
7. Removing tioLogic® easyClean from the Dental Washer Disinfector at the end of the programme and, if necessary, additionally dry it in a clean place.
8. Controlling instruments (p. 11 Care, checking, maintenance).
9. Mounting dismantled instruments and reinserting them in the intended places of tioLogic® easyClean.
10. Inserting tioLogic® easyClean in the corresponding sterilization container and sterilizing it.

Proof of basic suitability for effective automatic cleaning and disinfecting was provided by an independent, accredited test laboratory using a G 7836 GD disinfector (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh, Germany) and neodisher® Medizym cleaning agent (Dr. Weigert GmbH & Co. KG, Hamburg, Germany). The procedure described above was taken into account during the tests.

Care, checking.

Instruments should be checked after cleaning or cleaning/disinfection for corrosion, damaged surfaces, chipped edges and contamination. Damaged instruments should be discarded (p. 14 section Reusability of surgical instruments). Instruments that are still contaminated should be cleaned and disinfected again.

Maintenance.

Reassembly of instruments (p. 14 section Reusability of surgical instruments).

If possible, instrument oils should not be used. If oil is to be used, ensure that only instrument oils (white oil) are used, which – depending on the maximum sterilization temperature used – are approved for steam sterilization and certified biocompatible.

General instructions.

! Special measures are required with certain instruments.
Please refer to section Reusability of surgical instruments
■ p. 14!

Sterilization procedures.

Sterilization should only be completed using the sterilization procedures listed below; other sterilization procedures are not approved.

Steam sterilization.

- steam sterilizer in accordance with DIN EN 13060 or DIN EN 285
- validated in accordance with DIN EN ISO/ANSI AAMI ISO 17665 (formerly: DIN EN 554/ANSI AAMI ISO 11134) (valid commissioning and product-specific performance evaluation)
- maximum sterilization temperature 134 °C / 273 °F; including tolerance in accordance with DIN EN ISO/ANSI AAMI ISO 17665 (formerly: DIN EN 554/ANSI AAMI ISO 11134)
- sterilization time (exposure time at the sterilization temperature) minimum 5 min at 134 °C / 273 °F

Flash sterilization or gravitational method should never be used.

Do not use hot-air sterilization, X-ray sterilization, formaldehyde or ethylene oxide sterilization or plasma sterilization.

Proof of basic suitability for effective steam sterilization was provided by an independent, accredited test laboratory using a EuroSelectomat steam sterilizer (MMM Münchener Medizin Mechanik GmbH, Planegg, Germany) and the fractional vacuum process as well as a Systec V-150 steam sterilizer (Systec GmbH Labor-Systemtechnik, Wettenberg, Germany). The procedure described above was taken into account during the tests.

Correct storage.

After sterilization the tioLogic® easyClean has to be stored dry and dust free in the sterilization container.

Material resistance.

When choosing the cleaning agent and disinfectant, ensure that they do not contain the following components:

- organic, mineral or oxidizing acids
(maximum permitted pH 9.5, a neutral/ enzymatic cleaner is recommended)
- strong alkali
- organic solvents (e.g. alcohol, ether, ketones, benzene)
- oxidation agents (e.g. hydrogen peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic/ halogenated hydrocarbons
- heavy metal salts

Never clean instruments and sterilization trays with metal brushes or steel wool.

Reusability of surgical instruments.

Rotary instruments can be reused up to 30 to 40 times – with proper care and provided that they are not damaged or contaminated; the operator is deemed responsible for any further reuse or the use of damaged and/ or contaminated instruments. We do not accept any liability if these instructions are disregarded.

Torque ratchet.

Disassembly.

Fully unscrew the adjusting screw from the torque ratchet handle and remove the springs. Leave the stopper on the spring.

Loosen the screw on the ratchet head with the hex key in the adjusting screw using light pressure.

Remove the cover from the ratchet head. Remove the two components, the ratchet core and ratchet wheel, from the ratchet head.

The ratchet head and handle are in one piece; the screw is secured in the ratchet head and can be removed if required.

Removing the adjusting screw.



Opening the ratchet head.



Cover removed.

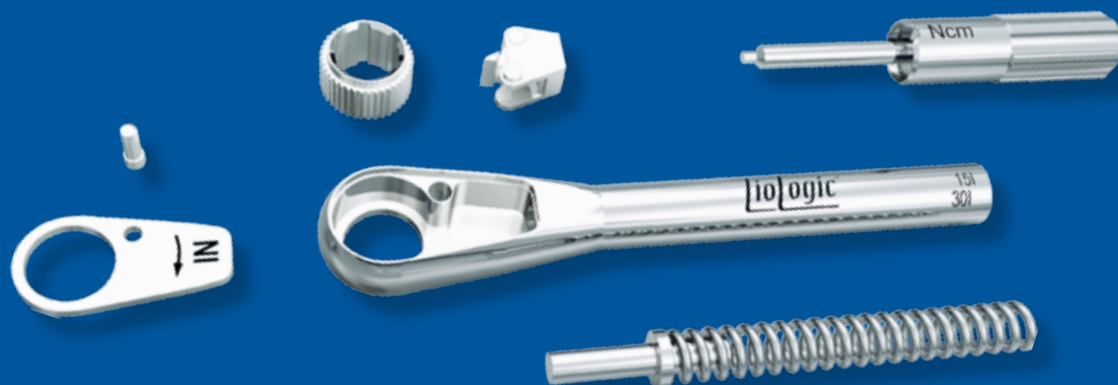


Ratchet wheel.



Ratchet wheel and ratchet core.





Assembly.

To ensure that the torque ratchet functions perfectly, adhere strictly to the following sequence when assembling the ratchet.

First insert the ratchet wheel into the open ratchet head. This should fit flush in the round recess; turn it 180° if necessary.

Then insert the ratchet core. This can also only be placed in a defined position so that the pawl sits between the teeth of the ratchet wheel. The contact zones between the teeth of the ratchet wheel and the ratchet core are easily lubricated. Always use the "Instrument Lubricant" (USDA H1 approved) supplied with the ratchet for lubrication. Remove any excess lubricant on the outer surface of the torque ratchet.

After the components have been inserted, replace the cover on the ratchet head and hold it in position. Turn the torque ratchet over and tighten the screw with the hex key until the cover is securely retained.

Insert the spring with the stopper towards the front into the ratchet handle and tighten the adjusting screw slightly.

Check the function after assembly.

Sterilization.

The torque ratchet should be fully assembled for sterilization.

If there are signs of corrosion, the components should be conditioned in a 0.1 % sodium nitrite solution prior to sterilization. Dry-heat sterilization (hot-air sterilizer) is not approved, as this can accelerate wear and tear on the spring, which affects the torque.

Insertion key.

Prior to cleaning, counter screws must be removed from the insertion keys and placed in the wire basket.

Dentaurum Group

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Subject to modifications

